K041983

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NOV 17 2004

510(k) SUMMARY

OPTICON MEDICAL

OPTION-*vm*™ Urinary Catheter

Submitter Information

Opticon Medical
7001 Post Road, Suite 100
Dublin, OH 43016

Primary Contact: Glenn D. Brunner, President
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Date Prepared: July 21, 2004

Device Name

Trade / Proprietary Name: OPTION-*vm*™ Urinary Catheter
OPTION-*vm*™ Urinary Catheter with Adaptor

Common / Usual Name: urinary catheter or Foley catheter

Classification Name: Catheter, Retention type, Balloon (product code EZL; 21 CFR 876.5130)

Predicate Device

- K023090, OPTION-*vf*™ Urinary Catheter
- K033830, OPTION-*vf*™ Urinary Catheter with Adaptor
- K760093, Bardex® Silicone Foley Catheter

Intended Use

The OPTION-*vm* is intended to provide drainage of the urinary bladder.

The OPTION-*vm* is indicated for use only for urinary bladder drainage in male patients: 1) who have acute conditions that require short-term (14 days or less) urinary management; 2) who are capable of operating the device in accordance with its instructions for use; and 3) for whom normal bladder cycling is not contraindicated.

Device Description

The OPTION-*vm* is an indwelling catheter that provides drainage of the urinary bladder. It is a sterile, single-use, disposable device that is to be prescribed by a physician and inserted and removed by an appropriate health care professional. The device is composed of biocompatible silicone elastomers, and consists of: a flexible shaft with two opposing eyelets in the proximal tip for urine entry, one internal lumen for urine drainage and a second lumen for balloon inflation; a retention balloon; a self-sealing balloon inflation microvalve port; and a urine discharge bulb with integral valve. The catheter may be used with the Continuous Drainage Adaptor accessory to provide continuous urinary drainage.

Comparison to Predicate Devices

The OPTION-*vm* and the predicate devices are all indwelling urinary catheters, which are used in the same anatomic location for the same purpose. The OPTION-*vm* is similar in design, materials of construction, physical dimensions, methods of insertion, maintenance and removal, etc. to the predicate catheters. It also follows equivalent principles of operation as the OPTION-*vf;* it uses the exact same components to form the identical integral valve assembly that allows the user to control bladder drainage, thus it can be initially used with the same Continuous Drainage Adaptor to provide continuous passive drainage of the urinary bladder into a standard urine drainage bag.

Supporting Information

Verification test results reported in this 510(k) application substantiate equivalence to the predicate devices. Thus, the OPTION-*vm* does not raise any new questions of safety or efficacy.

Conclusion

The OPTION-*vm* Urinary Catheter is substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 17 2004

Mr. Glenn D. Brunner
President
Opticon Medical
7001 Post Road, Suite 100
DUBLIN OH 43016

Re: K041983
Trade/Device Name: OPTION-*vm*™ Urinary Catheter
Regulation Number: 21 CFR §876.5130
Regulation Name: Urological catheter and accessories
Regulatory Class: II
Product Code: 78 EZL
Dated: October 6, 2004
Received: October 7, 2004

Dear Mr. Brunner:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K041983 Kat. V.

Device Name: OPTION-*vm*™ Urinary Catheter

Indications for Use: The OPTION-*vm* is indicated for use only for urinary bladder drainage in male patients: 1) who have acute conditions that require short-term (14 days or less) urinary management; 2) who are capable of operating the device in accordance with its instructions for use; and 3) for whom normal bladder cycling is not contraindicated.

(PLEASE DONOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

David B. Segroves

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K041983

(Optional Format 1-2-96)

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